



**Proven procedures, templates
and checklists for design control
compliance and 510(k)
submissions!**

This comprehensive package is based on our successful support of over two hundred companies and more than 20 years of industry experience.

- **Simplify premarket submission process**
- **Conform to FDA review checklists**
- **Use templates familiar to FDA reviewers**

With this package, you get a proven integrated solution to the FDA and CE Mark submission processes that will reduce submission review cycles.

***To order, please visit:
www.certifiedcompliance.com***

Sample Specifications for Design Control Compliance and Submissions



Templates

- FDA 510(k) Submission
- Technical File for CE Mark

Product Specifications

- Design and Development Plan
- Safety Risk Analysis (Fault Tree and Failure Modes & Effects Analysis)
- Requirements Specification
- Design Description
- Validation Test Procedure
- Test Summary Report

Design Procedures

- Design and Development Procedure
- Safety Risk Analysis Procedure

Checklists

- Review for Requirements Specification
- Review for Design Description
- Review for Test Procedure

**Certified Compliance Solutions, Inc.
16505 Avena Place Suite 203, San Diego, CA. 92128
www.certifiedcompliance.com • (858) 675-8200 • (858) 675-8201 (fax)**